Brexit means Brexit, but what about pharmacovigilance and the QPPV?

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Caveats

• The views expressed are personal and do not necessarily reflect those of my employer or any other organisation with which I am affiliated

• Questions, not answers
Timeline

23 June 2016
UK referendum – vote to leave the EU

2017

29 March
UK government triggers Article 50 – notice of intent to leave the EU

28 April
EMA & CMDh issues notice to Marketing Authorisation Holders

8 June
UK parliamentary election

19 June
Negotiations on leaving the EU started

November
New location of the EMA to be announced?

30 March 2019
UK leaves the EU?
Brexit scenarios

- Hard Brexit, no deal
- Hard Brexit, deal
- Soft Brexit, short transition period
- Soft Brexit, long transition period
- No Brexit
Regulatory control

Great Repeal Bill
European Medicines Agency
Medicines and Healthcare products Regulatory Agency
Co-operative
Stand-alone
Pharmacovigilance Risk Assessment Committee
European Court of Justice
Qualified Person for Pharmacovigilance

1,358 EEA QPPVs
153 registered in the UK¹
UK-based QPPVs
QPPV office
Contract QPPVs
Requirement for a UK QPPV?

1. EMA, 22 May 2017
Databases

EudraVigilance
ICSR reporting
Signal detection
Article 57 (xEVMPD)
Referrals and assessments

PSUR single assessment
PRAC referrals
Safety referrals (e.g. Article 31)
Risk management plans
Pharmacovigilance System Master File

Location
UK template?
Inspections

Information sharing with EEA competent authorities
Costs

Relocation of EMA
Impact on EMA projects
MHRA revenues
Relocation of MAH pharmacovigilance functions
What next?
Contact.

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Thank you for your attention.